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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,923	03/13/2002	Danny Zamir	02/23531	4686

7590 03/24/2004

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EXAMINER	
IBRAHIM, MEDINA AHMED	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,923	ZAMIR ET AL.	
	Examiner	Art Unit	
	Medina A Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *24-30* is/are withdrawn from consideration.

5)☒ Claim(s) *22 and 23* is/are allowed.

6)☒ Claim(s) *1-21 and 31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-23 and 31-33 filed 08 December 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is made FINAL.

Claims 1-33 are pending.

Claims 1-23 and 31-33 are under examination.

Claims 24-30 are withdrawn from consideration as being drawn to a non-elected invention.

Claim Objections

At claims 23, "a polynucleotide" should be changed to ---the polynucleotide--- because it refers to a previous claim.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2-3, 4, 7-11, 16-21 and 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 2, 4, 7, 9, 21, 31 and 33 are indefinite in the recitation of "utilizing" and "using" without any active, positive steps delimiting how this use is actually practiced. Dependent claims 10-11,16, 18-19 are included in the rejection.

Claims 3, 8, 20, and 32 are indefinite in the recitation of "hybridizable" which implies the polynucleotide may or may not hybridize to SEQ ID NO: 1, 4, or 6. It is unclear under what conditions the desired polynucleotide may not hybridize to the reference polynucleotide.

5. Claims 31-33 are indefinite as being incomplete for omitting an essential step, such omission amounting to a gap between the steps. See MPEP § 2172.01. It is unclear how the invertase polypeptide resulted in the plant tissue.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-21 and 31-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide comprising SEQ ID NO: 1, 4, 6 and polynucleotide encoding SEQ ID NO: 5, nucleic acid constructs, plant cells comprising said polynucleotide and a method of transforming a plant/plant cell with said polynucleotide, does not reasonably provide enablement for an isolated polynucleotide encoding a polypeptide having an invertase activity in an apoplastic environment, a polynucleotide having at least 80% identity or hybridizable to SEQ ID NO: 1, 4 or 6 or a portion thereof, or a polynucleotide encoding a polypeptide at least 80% homologous to SEQ ID NO:5, and a method of increasing a level of a monosaccharide in a plant tissue by expressing said polynucleotide in a plant. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant broadly claims an isolated polynucleotide encoding a polypeptide having an invertase activity in an apoplastic environment, a polynucleotide having at least 80% identity or hybridizable to SEQ ID NO: 1, 4 or 6 or a portion thereof, or a polynucleotide encoding a polypeptide at least 80% homologous to SEQ ID NO:5, wherein said polynucleotide encodes a polypeptide having apoplastic invertase activity. The claims are also drawn to a method of increasing a level of a monosaccharide in a plant tissue by expressing said polynucleotide in a plant tissue.

In re Wands (*858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant teaches identification of chromosomal region, which is associated with the high level of monosaccharide accumulation in *Lycopersicon pennellii* fruits by using marker-selected breeding of tomato plant introgression lines. Applicant also teaches isolation, cloning, and sequencing of SEQ ID NO: 1, 4, 6 encoding a polypeptide having invertase activity or SEQ ID NO: 5. Applicant also teaches prophetic methods of

increasing the level of monosccharide in a plant tissue by transformation with said polynucleotides (Examples 3-5).

Applicant has not provided guidance for the isolation of other polynucleotides from non-Lycopersicon sources encoding a polypeptide having apoplastic invertase activity, nor does Applicant teach DNA construct and plant cells comprising polynucleotides other than SEQ ID NO: 1, 4, or 6. Applicant does not teach a method for increasing a level of monosaccharide in a transgenic plant tissue with exemplified or non-exemplified sequences.

The state of the art for isolation of cDNA or genomic clones with specific function is highly unpredictable. Significant guidance is required with respect to hybridization and wash (or PCR) conditions, probe (or primer) sequences that will allow specific isolation of the target genes from all natural sources. In the absence of specific guidance, undue trial and error experimentation would be required to screen through the vast number of plant and non-plant cDNA and genomic clones to identify those that encode a functional apoplastic invertase, and also affect monosaccharide production of the plant. In addition, on page 10 of the specification, Applicant states that apoplastic invertases exist in plants in isozymes encoded by multiple gene family. It is unclear how many apoplastic inveratse genes a plant may contain, and the variation within the gene family.

In addition, Applicant has not provided guidance with respect to modifications in SEQ ID NO: 1, 4 or 6, that retain invertase activity. Applicant has not taught regions of the full-length sequence that are sufficient or necessary to encode a functional invertase or regions in SEQ ID NO: 5 that would tolerate modifications. In the absence of such

guidance, undue experimentation would be required to screen through the myriad of different polynucleotides having 80% identity to SEQ ID NO: 1, 4, 6 or those that hybridize thereto under the hybridization conditions as recited in the claims, or those that encode a polypeptide at least 80% homologous to SEQ ID NO: 5, to identify those that are effective in increasing monosaccharide production in specific tissue of a transgenic plant. When the *Wands* factors are considered, it is concluded that the teachings of the specification are not commensurate with the broad scope of the claims, and Applicant is not enabled throughout the scope of the claims.

Written Description

8. Claims 1-21 and 31-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated polynucleotide encoding a polypeptide having an invertase activity in an apoplastic environment, a polynucleotide having at least 80% identity or hybridizable to SEQ ID NO: 1, 4 or 6 or a portion thereof, or a polynucleotide encoding a polypeptide at least 80% homologous to SEQ ID NO:5, wherein said polynucleotide encodes a polypeptide having apoplastic invertase activity. The claims are also drawn to a method of increasing a level of a monosaccharide in a plant tissue by expressing said polynucleotide in a plant tissue. In contrast, Applicant

describes only SEQ ID NO: 1, 4, and 6 from a single plant species. These are genus claims

In *Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), the court stated:

An adequate written description of a DNA "requires a precise definition, such as by structure, formula, chemical name, or physical properties", not a mere wish or plan for obtaining the claimed chemical invention... Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself (43 USPQ2d at 1404).

The court held that held that human insulin-encoding cDNA is not described by prophetic example, which sets forth only a general method for obtaining the human cDNA:

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity...Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes...does not necessarily describe the DNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA....Accordingly, the specification does not provide a written description of human cDNA (43 USPQ2d at 1405).

The description of a single species of rat cDNA was held insufficient to describe the broad genera of vertebrate or mammalian insulin:

"In claims to genetic material...a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA', without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It doesn't define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function...does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is (43 USPQ2d at 1406).

The court continued:

"Thus...a cDNA is not defined by the mere name 'cDNA', even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the

cDNA...A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus". (43 USPQ2d at 1406). See, also where the court teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from the organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Firstly, claim 1 is described by function only, and there is known correlation between the structure and function of an inveratse DNA/polypeptide sequence. Applicant has not described structural element common to all apoplastic invertase that would allow one to predictably identify the structure/identity of the member of the genus claimed. Applicant has not described a single variant having both the structural and functional properties as recited in the claims. Therefore, the disclosure of SEQ ID NO: 1, 4, 6 does not provide adequate written description for all polynucleotides as broadly claimed. In addition, since Applicants has not described the polynucleotides as discussed above, nucleic acid constructs, transgenic plant cell comprising said polynucleotide, and methods that employ said polynucleotides are similarly not been described. See Written description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices).

Remarks

9. Claims 1-21 and 31-33 are deemed free of the prior art of record because the prior art does not teach or reasonably suggest an isolated polynucleotide of SEQ ID NO: 1, 4, 6, or encoding SEQ ID NO:5; a polynucleotide having at least 80% sequence identity or hybridizes thereto; a polynucleotide encoding a polypeptide having at least

80% homologous to SEQ ID NO: 5; nucleic acid construct and plant cells comprising said polynucleotide; nor that the prior art teaches a method that employs said polynucleotide.

10. Claims 22-23 are allowed.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Dickinson et al. (Plant Physiology, vol. 95, pp. 420-425 (1991) who teach slow growth phenotype of transgenic plants expressing apoplastic invertase.

Contact Information

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and After final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Mai
3/18/04

Medina A. Ibrahim